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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,238	07/17/2003	Edward Lynch	3068	2886

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EXAMINER

KRASS, FREDERICK F

ART UNIT PAPER NUMBER

1614

DATE MAILED: 03/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/623,238	Applicant(s) LYNCH ET AL.	
	Examiner Frederick F. Krass	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Previous Rejections

All previous rejections are withdrawn.

A new ground of rejection follows infra. Since same was not necessitated by Applicant's amendment, this action is NON-FINAL.

Claim Informalities

The following informalities are noted and should be corrected in responding to this Office Action:

- 1) Claim 1, third line, and claim 5, fourth line, in each instance "lesions" should be singularized.
- 2) Claim 1, twentieth line, the spelling of the word on that line should be corrected to read --- Carboxymethylcellulose ---
- 3) Claim 5, second line, immediately after the word "caries" there should be inserted --- and ---.
- 4) Claim 5, eighteenth line, the spelling of the word on that line should be corrected to read --- Poloxamer 407 ---

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Scope of Enablement Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of ozone in treating carious lesions, does not reasonably provide enablement for the use of an “oxidizing gas” generally. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Attention is directed to In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence or absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art,
- 7) the predictability of the art, and
- 8) the breadth of the claims.

The instant specification fails to provide guidance that would allow the

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skilled artisan to practice the instant invention without resorting to undue experimentation, as discussed in the subsections set forth infra.

1. The nature of the invention, state of the prior art, relative skill of those in the art, and the predictability of the art

The invention relates to the treatment of dental caries by treating carious lesions with a directed stream of gas. The state of the prior art is illustrated by WO 99/64020, which demonstrates the unpredictability of using a directed stream of gas for this purpose. See, e.g., page 3, lines 18-20, which states that the use of ozone in this manner was “unexpected”, based on its ability to penetrate carious tissue. See also the passage bridging the bottom of p. 5 to the top of p. 6, which outlines the unique mechanisms by which ozone achieves this function due to its peculiar breakdown in saliva.

The instant specification consistently describes the use of ozone throughout, and mentions “oxidizing gases” more generally at two points, and then only in passing. Note the use of the term at p. 11, line 8, and its later use at p. 15, lines 11-18. Significantly, the latter relies upon PCT/EP99/04035 (= WO 99/64020), incorporating it by reference as demonstrating the “effectiveness of an oxidizing gas such as ozone”. A review of that document reveals, however, that the only gas disclosed therein is ozone, with no mention of any other gas appearing.

2. The breadth of the claims

The claims are not limited to ozone, instead including all "oxidizing gases" (a term which presumably could include ordinary air).

3. The amount of direction or guidance provided and the presence or absence of working examples

The specification provides no specific direction or guidance for using any gas other than ozone. The working examples all use ozone.

4. The quantity of experimentation necessary

The instant specification fails to provide any direction or guidance for using any gas other than ozone. No evidence is provided that any gas other than ozone is available which possesses the admittedly unexpected properties which permit its use in treating carious lesions. The lack of adequate guidance from the specification or prior art with regard to the actual treatment of carious lesions fails to rebut the presumption of unpredictability extant in this art, as discussed in subsection "1)" supra. (As just one example, the examiner notes that ordinary air – arguably an "oxidizing gas", albeit a weak one – would not reasonably be expected to penetrate dentin and kill microorganisms under the conditions

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disclosed by the instant Application). Applicants fail to provide the guidance and information required to ascertain which gases, other than ozone, will be effective in treating carious lesions without resorting to undue experimentation.

Obviousness-Type Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 5 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 6,669,931 in view of WO 99/64020.

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The instant claims recite the treatment of carious lesions by administering ozone for a time sufficient to kill caries causing microorganisms in those lesions, followed by application of specific remineralizing formulations.

WO 99/64020 discloses the ozone treatment steps of the instant claims, but differs from same insofar as it is silent regarding use of a remineralizing formulation.

The conflicting claims recite the instantly claimed remineralizing compositions, rather than methods. They unambiguously characterize those compositions by intended use, however, reciting formulations "for the remineralization of teeth following ozone treatment." It would have been obvious on its face from that statement of intended use, therefore, to have administered the specific remineralizing formulations of those claims following a known ozone treatment, such as that of the secondary reference.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick F. Krass whose telephone number is 571-272-0580. The examiner's schedule is 9:30AM – 6:00PM, Monday through Friday.

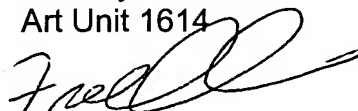
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The

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fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass
Primary Examiner
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A handwritten signature in black ink, appearing to read "Fred", is written over the printed name and title of the examiner.